

Environmental Protection Agency

§ 174.3

- 174.512 Coat Protein of Potato Virus Y; exemption from the requirement of a tolerance.
- 174.513 Potato Leaf Roll Virus Resistance Gene (also known as orf1/orf2 gene); exemption from the requirement of a tolerance.
- 174.514 Coat Protein of Watermelon Mosaic Virus-2 and Zucchini Yellow Mosaic Virus; exemption from the requirement for a tolerance.
- 174.515 Coat Protein of Papaya Ringspot Virus; exemption from the requirement of a tolerance.
- 174.516 Coat protein of cucumber mosaic virus; exemption from the requirement of a tolerance.
- 174.517 *Bacillus thuringiensis* Cry9C protein in corn; exemption from the requirement of a tolerance.
- 174.518 *Bacillus thuringiensis* Cry3Bb1 protein in corn; exemption from the requirement of a tolerance.
- 174.519 *Bacillus thuringiensis* Cry2Ab2 protein in corn and cotton; exemption from the requirement of a tolerance.
- 174.520 *Bacillus thuringiensis* Cry1F protein in corn; exemption from the requirement of a tolerance.
- 174.521 Neomycin phosphotransferase II; exemption from the requirement of a tolerance.
- 174.522 Phosphinothricin Acetyltransferase (PAT); exemption from the requirement of a tolerance.
- 174.523 CP4 Enolpyruvylshikimate-3-phosphate (CP4 EPSPS) synthase in all plants; exemption from the requirement of a tolerance.
- 174.524 Glyphosate Oxidoreductase GOX or GOXv247 in all plants; exemption from the requirement of a tolerance.
- 174.525 *E. coli* B-D-glucuronidase enzyme as a plant-incorporated protectant inert ingredient; exemption from the requirement of a tolerance.
- 174.526 Hygromycin B phosphotransferase (APH4) marker protein in all plants; exemption from the requirement of a tolerance.
- 174.527 Phosphomannose isomerase in all plants; exemption from the requirement of a tolerance.
- 174.529 *Bacillus thuringiensis* modified Cry1Ab protein as identified under OECD Unique Identifier SYN-IR67B-1 in cotton; exemption from the requirement of a tolerance.
- 174.530 *Bacillus thuringiensis* Cry2Ae protein in cotton; temporary exemption from the requirement of a tolerance.
- 174.531 Coat protein of plum pox virus; exemption from the requirement of a tolerance.
- 174.532 *Bacillus thuringiensis* eCry3.1Ab protein in corn; temporary exemption from the requirement of a tolerance.

Subpart X—List of Approved Inert Ingredients

- 174.700 Scope and purpose.
- 174.705 Inert ingredients from sexually compatible plant.

Subparts Y–Z [Reserved]

AUTHORITY: 7 U.S.C. 136–136y; 21 U.S.C. 346a and 371.

SOURCE: 66 FR 37814, July 19, 2001, unless otherwise noted.

Subpart A—General Provisions

§ 174.1 Scope and purpose.

The characteristics of plant-incorporated protectants such as their production and use in plants, their biological properties, and their ability to spread and increase in quantity in the environment distinguish them from traditional chemical pesticides. Therefore, plant-incorporated protectants are subject to some different regulatory requirements and procedures than traditional chemical pesticides. This part sets forth regulatory requirements, criteria, and procedures applicable to plant-incorporated protectants under FIFRA and FFDCA. When applied to plant-incorporated protectants, the definitions and regulations in this part supersede the regulations found in parts 150 through 180 of this chapter to the extent that the regulations conflict. Unless otherwise superseded by this part, the regulations in parts 150 through 180 of this chapter apply to plant-incorporated protectants.

§ 174.3 Definitions.

Terms used in this part have the same meaning as in FIFRA. In addition, the following terms have the meaning set forth in this section.

Active ingredient means a pesticidal substance that is intended to be produced and used in a living plant, or in the produce thereof, and the genetic material necessary for the production of such a pesticidal substance.

Administrator means the Administrator of the United States Environmental Protection Agency or his/her delegate.

Bridging crosses between plants means the utilization of an intermediate plant

in a cross to produce a viable zygote between the intermediate plant and a first plant, in order to cross the plant resulting from that zygote with a third plant that would not otherwise be able to produce viable zygotes from the fusion of its gametes with those of the first plant. The result of the bridging cross is the mixing of genetic material of the first and third plant through the formation of an intermediate zygote.

Cell fusion means the fusion *in vitro* of two or more cells or protoplasts.

Conventional breeding of plants means the creation of progeny through either: The union of gametes, *i.e.*, syngamy, brought together through processes such as pollination, including bridging crosses between plants and wide crosses, or vegetative reproduction. It does not include use of any of the following technologies: Recombinant DNA; other techniques wherein the genetic material is extracted from an organism and introduced into the genome of the recipient plant through, for example, micro-injection, macro-injection, micro-encapsulation; or cell fusion.

EPA means the United States Environmental Protection Agency.

Exudate means a substance gradually discharged or secreted across intact cellular membranes or cell walls and present in the intercellular spaces or on the exterior surfaces of the plant.

FFDCA means the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 *et seq.*).

FIFRA means the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (7 U.S.C. 136 *et seq.*).

Food includes articles used for food or drink by humans or other animals.

Food plant means a plant which either in part or *in toto*, is used as food.

Genetic material necessary for the production means both: Genetic material that encodes a substance or leads to the production of a substance; and regulatory regions. It does not include noncoding, nonexpressed nucleotide sequences.

Genome means the sum of the heritable genetic material in the plant, including genetic material in the nucleus and organelles.

In a living plant means inside the living plant, on the surface of the living

plant, or as an exudate from the living plant.

Inert ingredient, means any substance, such as a selectable marker, other than the active ingredient, where the substance is used to confirm or ensure the presence of the active ingredient, and includes the genetic material necessary for the production of the substance, provided that genetic material is intentionally introduced into a living plant in addition to the active ingredient.

Living plant means a plant, plant organ, or plant part that is alive, viable, or dormant. Examples of plant parts include, but are not limited to, seeds, fruits, leaves, roots, stems, flowers, and pollen.

Noncoding, nonexpressed nucleotide sequences means the nucleotide sequences are not transcribed and are not involved in gene expression. Examples of noncoding, nonexpressed nucleotide sequences include, but are not limited to, linkers, adapters, homopolymers, and sequences of restriction enzyme recognition sites.

Nucleic acids means ribosides or deoxyribosides of adenine, thymine, guanine, cytosine, and uracil; polymers of the deoxyribose-5'-monophosphates of thymine, cytosine, guanine, and adenine linked by successive 3'-5' phosphodiester bonds (also known as deoxyribonucleic acid); and polymers of the ribose-5'-monophosphates of uracil, cytosine, guanine, and adenine linked by successive 3'-5' phosphodiester bonds (also known as ribonucleic acid). The term does not apply to nucleic acid analogues (e.g., dideoxycytidine), or polymers containing nucleic acid analogues.

Pesticidal substance, means a substance that is intended to be produced and used in a living plant, or in the produce thereof, for a pesticidal purpose, during any part of a plant's life cycle (e.g., in the embryo, seed, seedling, mature plant).

Plant, for plant-incorporated protectants, means an organism classified using the 5-kingdom classification system of Whittaker in the kingdom Plantae. This includes, but is not limited to, bryophytes such as mosses, pteridophytes such as ferns, gymnosperms such as conifers, and

angiosperms such as most major crop plants.

Plant-incorporated protectant means a pesticidal substance that is intended to be produced and used in a living plant, or in the produce thereof, and the genetic material necessary for production of such a pesticidal substance. It also includes any inert ingredient contained in the plant, or produce thereof.

Produce thereof, when used with respect to plants containing plant-incorporated protectants only, means a product of a living plant containing a plant-incorporated protectant, where the pesticidal substance is intended to serve a pesticidal purpose after the product has been separated from the living plant. Examples of such products include, but are not limited to, agricultural produce, grains, and lumber. Products such as raw agricultural commodities bearing pesticide chemical residues are not “produce thereof” when the residues are not intended to serve a pesticidal purpose in the produce.

Recipient plant means the living plant in which the plant-incorporated protectant is intended to be produced and used.

Recombinant DNA means the genetic material has been manipulated *in vitro* through the use of restriction endonucleases and/or other enzymes that aid in modifying genetic material, and subsequently introduced into the genome of the plant.

Regulatory region means genetic material that controls the expression of the genetic material that encodes a pesticidal substance or leads to the production of a pesticidal substance. Examples of regulatory regions include, but are not limited to, promoters, enhancers, and terminators.

Sexually compatible, when referring to plants, means a viable zygote is formed only through the union of two gametes through conventional breeding.

Source means the donor of the genetic material that encodes a pesticidal substance or leads to the production of a pesticidal substance.

Vegetative reproduction means either:

(1) In seed plants, reproduction by apomixis, or

(2) In other plants, reproduction by fragmentation, or division of the somatic body.

Wide crosses means to facilitate the formation of viable zygotes through the use of surgical alteration of the plant pistil, bud pollination, mentor pollen, immunosuppressants, *in vitro* fertilization, pre-pollination and post-pollination hormone treatments, manipulation of chromosome numbers, embryo culture, or ovary and ovule cultures.

§ 174.9 Confidential business information claims for plant-incorporated protectant submissions.

Although it is strongly recommended that the submitter minimize the amount of data and other information claimed as Confidential Business Information (CBI), a submitter may assert a claim of confidentiality for all or part of the information submitted to EPA in a submission for a plant-incorporated protectant. (See part 2, subpart B of this chapter.) To assert such a claim, the submitter must comply with all of the following procedures:

(a) Any claim of confidentiality must accompany the information at the time the information is submitted to EPA. Failure to assert a claim at that time constitutes a waiver of confidentiality for the information submitted, and the information may be made available to the public, subject to section 10(g) of FIFRA, with no further notice to the submitter.

(b) Any claim of confidentiality must be accompanied, at the time the claim is made, by comments substantiating the claim and explaining why the submitter believes that the information should not be disclosed. The submitter must address each of the points listed in § 2.204(e)(4) of this chapter in the substantiation. EPA will consider incomplete all plant-incorporated protectant submissions containing information claimed as CBI that are not accompanied by substantiation, and will suspend any applicable review of such submissions until the required substantiation is provided.